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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,868	12/09/2003	Ruchika Singhal	1023-330US01	6697

28863 7590 02/24/2006  
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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,868	<b>Applicant(s)</b> SINGHAL ET AL.	
	<b>Examiner</b> William H. Matthews (Howie)	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-29-05, 2-3-06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 11-28-05 have been fully considered but they are not persuasive.

With regard to claim 1, Applicant states all references (Fischell, Berang, and Berang Application) lack 1) creating a pocket between scalp and skull, and 2) placing at least a portion of the device in the pocket. Examiner disagrees because a pocket (a space) is formed by each of the references. Although forming a flap (Berang and Berang Application) may be different from Applicant's method, these methods form a "pocket". Regarding Fischell, Figure 21 clearly shows portions 622 of the device placed in a pocket between the scalp and skull.

With regard to claim 2, Applicant contends Berang '914 and Berang Application lack first and second housings. Examiner disagrees because Applicant is attempting to define a "housing" beyond the reasonable interpretation of what is claimed. Berang '914 discloses first and second housings in the abstract. Berang Application shows first and second housings in Figure 2.

With regard to claim 6, Fischell shows the angle in figure 21 and Berang '914 shows the angle in figure 2.

With regard to claim 11, Applicant merely points to arguments raised with regard to limitations in claim 1. Examiner maintains the position set forth in the paragraphs above.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1,5-10,12,15,16 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. US PN 6,427,086.

3. Fischell et al. discloses in figures 21,26,27 and columns 31-35 a method of implanting an implantable medical device comprising creating a pocket and recess in the scalp for the implant which comprises a periphery having an angle of approximately 135 degrees, leads extending through bore holes in the skull, bone screw anchors, and means for adjusting the contour of the device to conform to the skull (RTV silastic lines 51-52 of col. 35).

4. Claims 1-3,5-7,9,10,12,15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PN 6,648,914.

5. Berrang et al. discloses in figures 1-3 and line 42 of col. 9 through line 25 of col. 14 a method of implanting an implantable medical device using local anesthetic comprising creating a pocket and recess in the scalp for the implant which comprises a periphery having an angle of approximately 135 degrees, leads, bone screw anchors,

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first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is between 4-8mm.

6. Claims 1-4,7,15 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PUB2003/0109903.

7. Berrang et al. discloses in figures 1 and 25 and paragraphs 46-48,54-56, and 80 a method of implanting an implantable medical device comprising creating a pocket in the scalp for the implant which comprises leads, first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is approximately 6mm.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell US PN 6,427,086 or Berrang et al. US PN 6,648,914 or Berrang et al. US PUB 2003/0109903.

10. Each of Fishcell and Berrang et al. independently meet the limitations of claim 11 but lack the express written disclosure of suturing the flap over the implant to complete

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the implantation procedure. The Examiner hereby takes Official Notice that suturing a skin flap to complete a surgical procedure is well known in the art.

11. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of suturing the flap to close the incision.

### ***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H Matthews 2-16-06  
Examiner AU 3738



**CORRINE McDERMOTT**  
**SUPERVISORY PATENT EXAMINER**  
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